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*C. R. Bard, Inc. and*  
*Bard Peripheral Vascular, Inc.*

**IN THE UNITED STATES DISTRICT COURT**  
**FOR THE DISTRICT OF ARIZONA**

IN RE: Bard IVC Filters Products Liability  
Litigation

No. 2:15-MD-02641-DGC

**DEFENDANTS' BRIEF  
REGARDING ADMISSIBILITY OF  
SIR GUIDELINES**

(Assigned to the Honorable David G.  
Campbell)

During the testimony of Dr. Clement Grassi, an evidentiary issue will arise as to whether the SIR Guidelines are substantively admissible and may be received as an exhibit.<sup>1</sup> As explained below, the SIR Guidelines should be admissible as substantive evidence -- not merely because they fall within the learned treatise exception under Fed. R. Evid. 803(18)<sup>2</sup> -- but because Bard intends to use the SIR Guidelines for non-hearsay purposes, including (a) notice, and (b) the relevant knowledge of the medical community. Because Bard intends to use the SIR Guidelines for non-hearsay purposes, the Court should permit the SIR Guidelines to be “received as an exhibit” and provided to the jury, and not merely “read into evidence.” *Id.*

### **ARGUMENT AND CITATION TO AUTHORITIES**

“[W]hether an out-of-court assertion is hearsay depends on its use “ at trial. David F. Binder, Hearsay Handbook § 1:9 (4th ed. 2015). Numerous federal courts have admitted and received as exhibits “learned treatise” evidence, including medical or scientific literature, when the literature is used for non-hearsay purposes, such as “to establish the . . . knowledge of the medical community.” *See, e.g., Buttice v. G.D. Searle & Co.*, 938 F. Supp. 561, 565–66 (E.D. Mo. 1996) (“The excerpts from medical texts are not inadmissible hearsay because they are not offered for the truth of the matters asserted therein, but rather to *establish the existence of medical literature and thus knowledge of the medical community* concerning IUD use and pelvic inflammatory disease at a particular point in time.” (emphasis added)); *see also Cook v. Navistar Int’l Transp. Corp.*, 940 F.2d 207, 213–14 (7th Cir. 1991) (industry publications pertaining to design standards in existence at time of product’s manufacture were not hearsay when offered to show actual and constructive knowledge of defendant); *Marsee v. United States Tobacco*

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<sup>1</sup> Dr. Clement Grassi is the original lead author of the SIR Guidelines.

<sup>2</sup> The SIR Guidelines, when used in the direct examination of Dr. Grassi, clearly falls within the hearsay exception of Rule 803(18). Statements within the SIR Guidelines will be relied upon by Dr. Grassi on direct examination, and Dr. Grassi will lay the foundation that the publication wherein the SIR Guidelines are published -- the Journal of Vascular and Interventional Radiology -- is a “reliable authority.” *See* Fed. R. Evid. 803(18)(A)&(B).

1 Co., 866 F.2d 319, 325–26 (10th Cir. 1989) (district court did not commit error in  
2 admitting scientific articles because they were not hearsay and were properly admitted on  
3 the issue of defendant’s notice); *Kershaw v. Sterling Drug, Inc.*, 415 F.2d 1009, 1011  
4 (5th Cir. 1969) (medical articles were not hearsay and were properly admitted to show  
5 that defendant should have known of existence and nature of particular disease).

6 Here, Bard intends to use the SIR Guidelines to demonstrate (a) notice, and (b)  
7 the relevant knowledge of the medical community. Bard does not intend to use the SIR  
8 Guidelines to prove the truth of the matters asserted in the document, and, thus, the SIR  
9 Guidelines are not hearsay. *See* Fed. R. Evid. 801(c)(2).

10 **First**, regarding notice, the SIR Guidelines demonstrate what Bard knew at  
11 various times regarding the reported and threshold rates of complications, such as  
12 fracture, migration, and perforation/penetration. Bard’s notice of these reported threshold  
13 rates is directly probative to whether the actions Bard took concerning the design and  
14 warnings for its G2 Filter were reasonable. Based on Bard’s notice of these reported and  
15 threshold rates in the SIR Guidelines, Bard took various pre- and post-market design and  
16 warning related actions, including striving to reduce its complication rates by making  
17 improvements from the Recovery Filter to the G2 Filter, and by communicating with  
18 doctors and FDA regarding Bard’s experiences in relation to the SIR Guidelines.

19 **Second**, the SIR Guidelines demonstrate the relevant knowledge of the medical  
20 community. They demonstrate the medical community’s knowledge that filter fracture,  
21 migration, perforation/penetration, and tilt are well-known complications within the  
22 medical community, at least as early as 2001 when the first version of the SIR Guidelines  
23 were published. And they demonstrate the medical community’s knowledge that these  
24 complications have been reported to occur at various rates as documented in the  
25 Guidelines. This medical community knowledge is, again, directly probative to whether  
26 the actions Bard took concerning the design and warnings for its G2 Filter were  
27 reasonable. For instance, because the incidence rates within the EVEREST clinical trial  
28 for fracture, migration, and perforation were all within the SIR Guidelines’ reported

1 rates,<sup>3</sup> Bard reported the numbers of complications to FDA and in its IFU for the G2,<sup>4</sup>  
 2 but it did not otherwise change its G2 warnings. Bard's warning-related decision was  
 3 reasonable in light of the medical community's knowledge of the reported rates for these  
 4 complications.

### 5 CONCLUSION

6 For the reasons stated above, the SIR Guidelines should be admitted as  
 7 substantive evidence because Bard is not using them for the truth of the matters stated in  
 8 therein. Instead, Bard intends to use the SIR Guidelines as evidence to prove notice, and  
 9 to prove the relevant knowledge of the medical community.

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26 <sup>3</sup> See Defense Exhibit 5340 (G2 510(k) dated October 31, 2007) at page 5340.0408. This  
 27 exhibit was admitted on March 26, 2018, during the testimony of Mr. John Van Vleet.

28 <sup>4</sup> See Defense Exhibit 5283 (G2 IFU). This exhibit was admitted on March 26, 2018,  
 during the testimony of Mr. John Van Vleet.

**CERTIFICATE OF SERVICE**

I hereby certify that on this 27th day of March, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Richard B. North, Jr.  
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